



EXPRESS MAIL LABEL NO.: EV 329 632 850 US

PATENT APPLICATION  
Docket No.: 7678.791

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of )  
Peter M. Allred and Neil T. Jessop )  
Serial No. 10/646,484 ) Art Unit  
Filed: August 22, 2003 ) Unknown  
For: COMPOSITIONS AND DEVICES HAVING A )  
TRAY- LIKE CONFIGURATION FOR )  
DELIVERING AN ORAL MEDICAMENT AND )  
METHODS OF MANUFACTURING AND )  
USING SUCH COMPOSITIONS AND DEVICES )  
Examiner: Unknown )

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

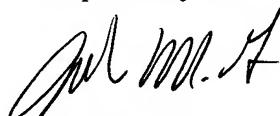
Sir:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form PTO-1449 which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). While no representation is made that any of these references may be "prior art" within the meaning of that term under 35 U.S.C. §§ 102 or 103, the enclosed list of references is disclosed so as to fully comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the enclosed art is the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

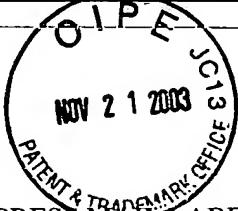
Dated this 21<sup>st</sup> day of November, 2003.

Respectfully submitted,



John M. Guynn  
Attorney for Applicant  
Registration No. 36,153  
Customer No. 022913

JMG:kcs  
W:\7678\791\KCS0000000651V001.doc



EXPRESS MAIL LABEL NO.: EV 329 632 850 US

Form PTO-1449

Sheet 1 of 6

Applicant: Peter M. Allred, et al.

Serial No.: 10/646,484

Att'y Docket No.: 7678.791

Filing Date: August 22, 2003

Group: Unknown

Confirmation No.: Unknown

For: COMPOSITIONS AND DEVICES HAVING A TRAY-LIKE CONFIGURATION FOR  
DELIVERING AN ORAL MEDICAMENT AND METHODS OF MANUFACTURING  
AND USING SUCH COMPOSITIONS AND DEVICES

INFORMATION DISCLOSURE CITATIONS MADE BY APPLICANT

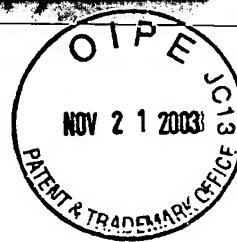
U.S. Patent Application Publication Documents

Examiner Initial*	Patent Number	Publication Date	Name	Class	Sub Class	Filing Date
_____ A1.	US 2001/0046654	11/29/01	Zavitsanos et al.	433	32	03/23/01
_____ A2.	US 2002/0006387	01/17/02	Sagel et al.	424	53	05/24/01
_____ A3.	US 2002/0006388	01/17/02	Sagel et al.	424	53	05/24/01
_____ A4.	US 2002/0012685	01/31/02	Sagel et al.	424	401	05/24/01
_____ A5.	US 2002/0018754	02/14/02	Sagel et al.	424	49	03/15/99
_____ A6.	US 2002/0081555	06/27/02	Wiesel	433	215	02/04/02
_____ A7.	US 2002/0164292	11/07/02	Peterson et al.	424	53	01/25/02
_____ A8.	US 2002/0182154	12/05/02	McLaughlin	424	53	08/08/01
_____ A9.	US 2002/0187111	12/12/02	Xu et al.	424	53	02/22/02
_____ A10.	US 2002/0187112	12/12/02	Xu et al.	424	53	02/22/02
_____ A11.	US 2003/0003421	01/02/03	Besenheider et al.	433	215	07/02/01
_____ A12.	US 2003/0012747	01/16/03	Peterson	424	53	03/23/01
_____ A13.	US 2003/0036037	02/20/03	Zavitsanos et al.	433	215	08/05/02
_____ A14.	US 2003/0044631	03/06/03	Sagal et al.	428	548	08/22/02

Examiner:

Date Considered:

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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Sheet 2 of 6

Applicant: Peter M. Allred, et al.

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<u>      </u> A15.	US 2003/0068284	04/10/03	Sagel et al.	424	53	12/17/02
<u>      </u> A16.	US 2003/0068601	04/10/03	Zavitsanos et al.	433	215	11/20/02
<u>      </u> A17.	US 2003/0082114	05/01/03	Kim et al.	424	53	02/13/01
<u>      </u> A18.	US 2003/0133884	07/17/03	Chang et al.	424	53	09/13/02
<u>      </u> A19.	US 2003/0194382	10/16/03	Chang et al.	424	53	06/20/02
<u>      </u> A20.	US 2003/0198606	10/23/03	Kim et al.	424	53	05/27/03

U.S. Patent Documents

<u>Examiner Initial*</u>	<u>Patent Number</u>	<u>Issue Date</u>	<u>Name</u>	<u>Class</u>	<u>Sub Class</u>	<u>Filing Date</u>
<u>      </u> A21.	2,835,628	05/20/58	Saffir	167	84	04/01/57
<u>      </u> A22.	3,688,406	09/05/72	Porter et al.	32	40 R	08/07/70
<u>      </u> A23.	Re. 33,093	10/17/89	Schiraldi et al.	424	676	11/16/88
<u>      </u> A24.	5,112,225	05/12/92	Diesso	433	48	08/02/91
<u>      </u> A25.	5,310,563	05/10/94	Curtis et al.	424	616	10/25/91
<u>      </u> A26.	5,326,685	07/05/94	Gaglio et al.	433	215	09/14/92
<u>      </u> A27.	5,346,061	09/13/94	Newman et al.	206	221	08/06/92
<u>      </u> A28.	5,425,953	06/20/95	Sintov et al.	424	404	04/22/92

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Sheet 3 of 6

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_____ A29.	5,575,654	11/19/96	Fontenot	433	215	03/15/94
_____ A30.	5,562,449	10/08/96	Jacobs et al.	433	215	04/18/95
_____ A31.	5,611,687	03/18/97	Wagner	433	80	11/06/95
_____ A32.	5,616,027	04/01/97	Jacobs et al.	433	37	04/15/96
_____ A33.	5,639,445	06/17/97	Curtis et al.	424	49	01/06/94
_____ A34.	5,707,235	01/13/98	Knutson	433	213	04/03/95
_____ A35.	5,711,935	01/27/98	Hill et al.	424	49	05/10/94
_____ A36.	5,769,633	06/23/98	Jacobs et al.	433	37	03/05/97
_____ A37.	5,816,802	10/06/98	Montgomery	433	80	09/25/95
_____ A38.	5,846,058	12/08/98	Fischer	433	216	09/26/96
_____ A39.	5,863,202	01/26/99	Fontenot et al.	433	215	08/12/96
_____ A40.	5,879,691	03/09/99	Sagel et al.	429	401	06/06/97
_____ A41.	5,891,453	04/06/99	Sagel et al.	424	401	03/17/98
_____ A42.	5,894,017	04/13/99	Sagel et al.	424	401	06/06/97
_____ A43.	5,924,863	07/20/99	Jacobs et al.	433	80	06/11/97
_____ A44.	5,980,249	11/09/99	Fontenot	433	80	06/11/98
_____ A45.	5,989,569	11/23/99	Dirksing et al.	424	401	06/06/97

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Sheet 4 of 6

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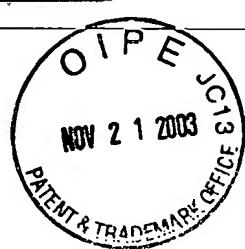
_____ A46.	6,045,811	04/04/00	Dirksing et al.	424	401	06/06/97
_____ A47.	6,096,328	08/01/00	Sagel et al.	424	401	11/19/98
_____ A48.	6,106,293	08/22/00	Wiesel	433	215	12/04/98
_____ A49.	6,126,443	10/03/00	Burgio	433	215	12/21/98
_____ A50.	6,136,297	10/24/00	Sagel et al.	424	49	03/17/98
_____ A51.	6,142,780	11/07/00	Burgio	433	80	06/15/99
_____ A52.	6,155,832	12/05/00	Wiesel	433	215	10/08/99
_____ A53.	6,183,251	02/06/01	Fischer	433	48	02/26/99
_____ A54.	6,197,331	03/06/01	Lerner et al.	424	448	07/24/97
_____ A55.	6,247,930	06/19/01	Chiang et al.	433	80	09/29/99
_____ A56.	6,274,122	08/14/01	McLaughlin	424	53	05/17/99
_____ A57.	6,277,458	08/21/01	Dirksing et al.	424	42.3	03/15/99
_____ A58.	6,280,196	08/28/01	Berghash	433	215	10/16/00
_____ A59.	6,287,120	09/11/01	Wiesel	433	215	03/27/00
_____ A60.	6,322,360	11/27/01	Burgio	433	80	10/22/99
_____ A61.	6,343,932	02/05/02	Wiesel	433	215	11/13/00
_____ A62.	6,419,903	07/16/02	Xu et al.	424	49	08/20/01

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Examiner:

Date Considered:

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Sheet 5 of 6

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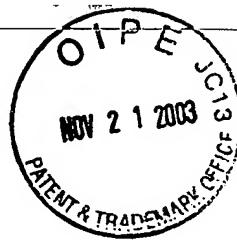
_____ A63.	6,419,906	07/16/02	Xu et al.	424	53	03/12/01
_____ A64.	6,435,873	08/20/02	Burgio	433	80	10/10/00
_____ A65.	6,440,396	08/27/02	McLaughlin	424	49	02/29/00
_____ A66.	6,458,380	10/01/02	Leaderman	424	443	11/09/00
_____ A67.	6,461,158	10/08/02	Sagel et al.	433	30	08/14/00
_____ A68.	6,497,575	12/24/02	Zavitsanos et al.	433	215	11/21/01
_____ A69.	6,500,408	12/31/02	Chen	424	53	01/27/01
_____ A70.	6,503,486	01/07/03	Xu et al.	424	53	02/22/02
_____ A71.	6,506,053	01/14/03	Wiesel	433	215	02/04/02
_____ A72.	6,514,483	02/04/03	Xu et al.	424	53	02/22/02
_____ A73.	6,514,484	02/04/03	Rajaiah et al.	424	53	02/28/02
_____ A74.	6,551,579	04/22/03	Sagel et al.	424	53	05/29/01

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Examiner:

Date Considered:

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Form PTO-1449

Sheet 6 of 6

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Serial No.: 10/646,484

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Att'y Docket No.: 7678.791

Group: Unknown

### References Cited by Applicants

While the filing of Information Disclosure Statements is voluntary, the procedure is governed by the guidelines of Section 609 of the Manual of Patent Examining Procedure and 37 C.F.R. §§ 1.97 and 1.98. To be considered a proper Information Disclosure Statement, Form PTO-1449 shall be accompanied by a copy of each listed patent or publication or other item of information and a translation of the pertinent portions of foreign documents (if an existing translation is readily available to the applicant), an explanation of relevance of each reference not in the English language, and should be submitted in a timely manner as set out in MPEP Sec. 609.

Examiners will consider all citations submitted in conformance with 37 C.F.R. § 1.98 and MPEP Sec. 609 and place their initials adjacent the citations in the spaces provided on this form. Examiners will also initial citations not in conformance with the guidelines which may have been considered. A reference may be considered by the Examiner for any reason whether or not the citation is in full conformance with the guidelines. A line will be drawn through a citation if it is not in conformance with the guidelines AND has not been considered. A copy of the submitted form, as reviewed by the Examiner, will be returned to the applicant with the next communication. The original of the form will be entered into the application file.

Each citation initialed by the Examiner will be printed on the issued patent in the same manner as references cited by the Examiner on Form PTO-892.

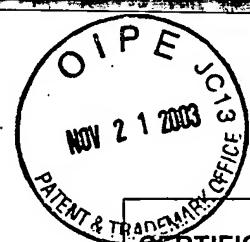
The reference designations "A1," "A2," etc. (referring to Applicant's reference 1, Applicant's reference 2, etc.) will be used by the Examiner in the same manner as Examiner's reference designations "A," "B," "C," etc. on Office Action Form PTO-1142.

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Examiner:

Date Considered:

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)**

Applicant(s): Peter M. Allred, et al.

Docket No.  
7678.791

Serial No. 10/646,484	Filing Date August 22, 2003	Confirmation No. Unknown	Examiner Unknown	Group Art Unit Unknown
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Invention: : COMPOSITIONS AND DEVICES HAVING A TRAY-LIKE CONFIGURATION FOR  
DELIVERING AN ORAL MEDICAMENT AND METHODS OF MANUFACTURING AND USING SUCH  
COMPOSITIONS AND DEVICES

I hereby certify that the Transmittal letter (2 pages) (in triplicate); Information Disclosure Statement (2 pgs); Form PTO-1449 Listing all Cited References (6 pgs); and postcard are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on.

November 21, 2003

Kendell Steele

*(Typed or Printed Name of Person Mailing  
Correspondence)*



*(Signature of Person Mailing Correspondence)*

**US 329 632 850 US**

*("Express Mail" Mailing Label Number)*

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EXPRESS MAIL LABEL NO.: EV 329 632 850 US

PATENT APPLICATION

Docket No.: 7678.791

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

## TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing and pursuant to 37 C.F.R. § 1.97 is an Information Disclosure Statement.

Enclosed also are the following designated documents, as required under 37 C.F.R. §§ 1.97 and 1.98:

- Form PTO-1449 list of seventy-four (74) references submitted for consideration.
- Legible copies of the listed references or their relevant portions.
- All English translations of each non-English reference, if any, within the possession, custody, control or availability of anyone designated in 37 C.F.R. § 1.56(c) (see 37 C.F.R. § 1.98(c)).

The following are included within the Information Disclosure Statement if applicable and as required under 37 C.F.R. § 1.98:

- Concise explanation of relevance of each reference not in English and unaccompanied by an English translation.

- Statement that certain listed references not enclosed are substantially cumulative of an enclosed reference.
- Statement that certain listed references not enclosed were previously cited by or submitted to the Office in the identified prior application which is relied upon for an earlier filing date under 35 U.S.C. § 120.
- Legible Copies of previously filed Information Disclosure Statement for application Serial No. \_\_\_\_\_, filed \_\_\_\_\_.

In order to secure consideration of the items designated above, one or more of the following, if required, is also enclosed:

- Promptness Certification.
- Check No. \_\_\_\_\_ in the amount of \$240.00 constituting submission fee under 37 C.F.R. 1.17(p);
- Petition for Consideration and Check No. \_\_\_\_\_ in the amount of \$\_\_\_\_\_.
- In the event that 37 C.F.R. § 1.97(c) applies and the Examiner is not satisfied that the Promptness Certification meets the requirements of 37 C.F.R. § 1.97(e), or in any other event remediable by a fee, please credit any over payment or charge any additional fees to Deposit Account No. 23-3178 of the undersigned.

Dated this 21<sup>st</sup> day of November, 2003.

Respectfully submitted,



John M. Guynn  
Attorney for Applicant  
Registration No. 36,153  
Customer No. 022913